IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

GRETCHEN S. STUART, M.D., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	CIVIL ACTION
	)	
RALPH C. LOOMIS, M.D., et al.,	)	Case No. 1:11-cv-00804
	)	
Defendants.	)	

DECLARATION OF ANNE DRAPKIN LYERLY, M.D., M.A.,
IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

ANNE D. LYERLY, M.D., M.A., declares and states the following:

1. I am a board-certified Obstetrician/Gynecologist and a bioethicist.

2. I am licensed to practice medicine in North Carolina and am a fellow of the American College of Obstetricians and Gynecologists. I graduated from Duke University Medical School with an M.D. in 1995 and from Georgetown University with an M.A. in Philosophy in 2004. After my residency in obstetrics and gynecology at Duke University, I completed the Greenwall Fellowship in Bioethics and Health Policy at Johns Hopkins University and Georgetown University from 1999 to 2001. This fellowship provides training specifically in bioethics and health policy.

3. I am currently on the faculty of the University of North Carolina School of Medicine, where I am Associate Professor in the Department of Social Medicine and Associate Director of the Center for Bioethics. My responsibilities at the University of North Carolina School of Medicine include conducting research, writing and speaking,

mentoring students and junior faculty, building the new Center for Bioethics with the Director, participating in Departmental and Center activities (seminars, programs, recruitment), and teaching.

4. Prior to joining UNC, I was on the faculty at Duke University, where I taught and practiced obstetrics and gynecology in the School of Medicine and bioethics at the Trent Center for Bioethics, Humanities, and History of Medicine. My responsibilities at Duke included patient care (general gynecology, directing the Miscarriage Clinic), teaching students and residents, and conducting research.

5. As director of the miscarriage clinic at Duke, I regularly participated in the informed consent process for my patients, including for procedures such as dilation and curettage or manual vacuum aspiration following a miscarriage, as well as dilation and curettage or manual vacuum aspiration to remove a pregnancy that the patient has learned is not viable. For example, in some pregnancies, women may discover that an embryo or fetus that previously had a heartbeat has lost the heartbeat. In other pregnancies, a patient may learn that she has a "blighted ovum," or a gestational sac that has formed without an embryo. In both of these situations, the pregnancy is not viable, and the patient has the option of having a physician remove the pregnancy surgically, of using medication to help the body expel the pregnancy, or of waiting for the body itself to expel the pregnancy as a miscarriage. Some patients choose dilation and curettage or manual vacuum aspiration in such circumstances. From a surgical standpoint, dilation and curettage or manual vacuum aspiration involves the same steps for the doctor and the

patient as a first-trimester abortion. Therefore, these procedures are technically very similar.

6. As a general obstetrician-gynecologist, I also have participated in the informed consent process for a range of other procedures in obstetrics and gynecology.

7. I have authored or co-authored dozens of publications on issues in bioethics, especially issues relating to reproductive health. I have received numerous research grants as principle investigator or co-investigator in the field of bioethics, including from the National Institutes of Health and Duke University. Informed consent is one of the central concerns of bioethics. My research has included issues surrounding informed consent in particular.

8. My experience and credentials, both in obstetrics and gynecology and in bioethics, are set forth in more detail on my *curriculum vitae*, a true and accurate copy of which is attached hereto as Exhibit A.

9. The opinions expressed in this declaration are my expert opinions based on my nearly twenty years of experience treating and consulting with patients as an obstetrician and gynecologist. Additionally, my opinions are based on knowledge I have obtained through my education, ongoing review of the relevant professional literature, my discussions with colleagues, and my attendance at conferences related to the topics discussed below.

North Carolina's Woman's Right to Know Act

10. I have reviewed North Carolina's Woman's Right to Know Act ("the Act"). I understand that the Act adds abortion-specific requirements for obtaining informed consent from a patient (in Section 90-21.82) and adds a "display of real-time view requirement" (in Section 90-21.85). I understand that Section 90-21.85 imposes the following new obligations on abortion providers: (a) the physician who is to perform an abortion or a "qualified technician" (as defined in the Act) must perform "an obstetric real-time view of the unborn child" (as defined in the Act) on the pregnant woman at least four hours before the abortion; (b) that person must "display the images so that the pregnant woman may view them;" (c) that person must provide to the pregnant woman a "simultaneous explanation of what the display is depicting, which shall include the presence, location, and dimensions of the unborn child within the uterus and the number of unborn children depicted;" (d) that person must provide the pregnant woman with a "medical description of the images, which shall include the dimensions of the embryo or fetus and the presence of external members and internal organs, if present and viewable;" and (e) that person must obtain a written certification from the pregnant woman, in which she "shall indicate whether or not she availed herself of the opportunity to view the image." Section 90-21.85(a). Section 90-21.85 also states that it shall not "be construed to prevent a pregnant woman from averting her eyes from the displayed images or from refusing to hear the simultaneous explanation and medical description." Section 90-21.85(b).

11. Section 90-21.85 obligates physicians to subject patients to an experience – of visual images of the fetus and explanations of images – even when the patient does not want that experience. Such a requirement violates the most basic principles of medical ethics, undermines informed consent and the informed decision-making process, and inflicts significant harm on the physician-patient relationship.

12. Central tenets of medical ethics include: (i) the obligation to respect the patient's autonomy; (ii) to act upon the patient only with her consent; (iii) to act in the patient's interests as a competent patient has defined those interests (beneficence); and, (iv) not to inflict harm on the patient (non-maleficence). [*See, e.g.*, Beauchamp T. and Childress J., *Principles of Medical Ethics*, New York: Oxford University Press, 6th ed. 2009; American College of Obstetricians and Gynecologists Committee on Ethics, Committee Opinion #390: Ethical Decision Making in Obstetrics and Gynecology, Washington DC: ACOG, 2007, reaffirmed 2010]. It is my opinion that Section 90-21.85 would require physicians to violate all of these tenets.

13. The purpose of the informed consent process is to ensure that the patient's consent consists of an informed and autonomous decision and to make it possible to respect the individual patient's views about what she wants to do. [*See, e.g.*, Faden R. and Beauchamp T., *A History and Theory of Informed Consent*, New York: Oxford University Press, 1986; American College of Obstetricians and Gynecologists Committee on Ethics, Committee Opinion #439: *Informed Consent*, Washington DC: ACOG, 2009].

14. The practitioner's role in the informed consent process is to provide the patient with information that will allow the patient to make an autonomous choice. This information includes material facts about the nature of the proposed procedure, the patient's indications for the procedure, the procedure's medical risks and benefits, and alternatives to the procedure. [*See, e.g., id.*].

15. Respecting patient autonomy means viewing the patient as someone who can make decisions for herself and includes the obligation on the part of the practitioner to ensure that the patient can act on her own decisions and values. Respecting patient autonomy also requires that the practitioner avoid taking action contrary to the wishes of a competent patient and avoid ignoring, insulting or demeaning the patient. [*See, e.g.*, Beauchamp and Childress, *Principles of Biomedical Ethics*, Ch. 4, New York: Oxford University Press, 6th ed. 2009].

16. Respecting autonomy also requires that the physician protect the patient from controlling influences and refrain from actions that are coercive. Coercive acts are those that aim to compel an individual to act in an involuntary manner. [*See, e.g., id.*].

17. Values and beliefs also may be discussed in the informed consent process in response to an expressed desire or need for such discussion by the patient, but forced discussion of values may alternatively disrespect autonomy. [*See, e.g.*, Emmanuel and Emmanuel, Four Models of the Physician Patient Relationship, *JAMA*, 1992; 267(16):2221-6]. When a patient declines discussion of matters of value, it is not appropriate for a physician to interject his or her own value-based views, those of the

government or of any other third party into the informed consent discussion. To do so would violate the ethical requirement of respect for the patient's autonomy.

18. Additionally, the extent and nature of the information given to the patient in the informed consent process should be tailored to the particular patient's needs and concerns. In order to provide such individualized care, the physician must listen to the patient to discern what information is material and helpful to her and must aim to provide the level and type of information that will optimize her understanding and respect her autonomy. [*See, e.g.*, Beauchamp and Childress, *Principles of Biomedical Ethics*, Ch. 4, New York: Oxford University Press, 6th ed. 2009].

19. If a competent patient says that she does not want to receive particular information, that decision must be respected. Providing a patient with information she has said that she does not want to receive disrespects the patient's autonomy and has the potential to undermine her ability to make a choice consistent with her values. [*See, e.g.*, Gostin LO, Informed Consent, Cultural Sensitivity, and Patient Autonomy, *JAMA*, 1995; 274(10):844-5]. Patients can autonomously opt to be provided with less than maximal information without violation of – and in the interests of ensuring – their ability to provide informed consent. [*See, e.g.*, Woodcock S., Abortion Counseling and the Informed Consent Dilemma, *Bioethics* 2011; 25:495-504].

20. Additionally, a physician should not be placed in the position of requiring a patient to consider information that the physician, in his or her medical judgment, concludes is not medically relevant. If a patient has a question about such information, a

physician should make his or her best effort to respond to the patient's question. However, if a patient indicates that she does not wish to hear information that the physician agrees is not medically appropriate or if a patient states that such information is not relevant to her decision, it would violate the principle of respect for patient autonomy for the physician to forcibly deliver such information to the patient.

21. In my past experience taking care of patients in the miscarriage clinic at Duke and in my general gynecology practice, whether the opportunity to view an ultrasound before uterine evacuation was relevant, harmful or beneficial to the patient depended very much on the individual patient and her choices. For patients who requested the ultrasound, it could be beneficial as a tool to confirm that the fetus had died (even when a prior ultrasound had confirmed this fact). For other patients, however, an ultrasound could be experienced as traumatic because it reminded them of the moment they found out they had miscarried. In both sets of situations, the ultrasound served to shape the patient's experience – in the former situation, it served to reassure; but in the latter, if the patient had been required to view an ultrasound, the experience would merely have amplified the emotional pain of the procedure. My experiences support contemporary views on informed consent: that more explicit and more specific information is not necessarily more effective, but rather that effective informed consent must be highly context-sensitive and responsive to the needs of the patient in her particular case. [*See, e.g.*, Manson NC and O'Neill O., *Rethinking Informed Consent in*

Bioethics, Cambridge: Cambridge University Press, 2007; McLeod C. *Self-Trust and Reproductive Autonomy*. Cambridge MA: MIT Press, 2002].

22. To the extent Section 90-21.85 requires physicians to act over their patients' objections, for at least some patients, this refusal to respect their wishes will be interpreted as demeaning to them. Accordingly, it is my opinion that Section 90-21.85 will require physicians to violate the ethical principle of respecting patient autonomy.

23. To the extent Section 90-21.85 requires physicians to subject a patient to pictures and descriptions of the embryo or fetus that the patient has indicated that she does not want, it is my opinion that Section 90-21.85 will force physicians to act upon the patient without the patient's consent, and therefore, violate medical ethics.

24. Additionally, to the extent Section 90-21.85 requires a physician to subject a patient to an experience or information that the patient has declined to accept, the law will be detrimental to the physician-patient relationship and the patient's care. Specifically, it will put the patient in a position of protecting or defending herself against something her physician is doing or saying to her. This would be an unwarranted intrusion into the patient's personal decision-making process, and it would create a difficult dynamic of distrust for the provision of health care to a patient. Trust and respect are critical to an ethically sound physician-patient relationship.

25. Section 90-21.85 also threatens the fiduciary duty owed to patients by physicians, by virtue of their professional role. This duty requires the physician to act in

the patient's interests (as those interests have been expressed by a competent patient) and to seek to ensure that the patient is safe.

26. Finally, Section 90-21.85 forces physicians to violate the principle of non-maleficence, the duty not to inflict harm on a patient. Subjecting a patient to an unwanted experience of receiving visual and auditory information about the embryo or fetus in advance of an abortion has the potential to inflict harm and directly violate the obligation to avoid harming the patient. Section 90-21.85 does not allow for physician discretion or any exceptions (other than for a medical emergency) to avoid putting physicians in the position of harming their patients.

27. I am not aware of any other procedure in the field of obstetrics and gynecology where medical professionals have concluded that it is necessary as an ethical matter to require a pregnant woman to view an image of her own embryo or fetus in order to assure that the patient's decision-making is informed.

28. For instance, chorionic villus sampling (CVS) and amniocentesis are standard medical procedures that are regularly chosen by pregnant women in order to determine if there are any genetic abnormalities in the fetus. CVS is generally performed at approximately 10 to 12 weeks gestation and amniocentesis is generally performed at approximately 15 to 17 weeks gestation. These procedures are invasive, requiring entry into the woman's uterus, and, for an amniocentesis, entry with a needle through the woman's abdominal wall into the amniotic sac. The procedures also carry an

approximately 1 in 100 and 1 in 200 risk, respectively, of miscarriage and therefore death of the fetus.

29. A patient choosing CVS or amniocentesis, which carries risk for both the woman and the fetus, is not required to view an ultrasound of her own fetus in advance of the procedure, and physicians are not required to deliver a description of the fetus to the patient before the procedure. Further, it is my opinion that any requirement to force women in such circumstances to view an ultrasound in advance or to require physicians to deliver a description of the ultrasound would violate medical ethics.

30. Similarly, I am not aware of any other procedure in the medical field where medical opinion provides that it is necessary as an ethical matter for the patient to view an image of his or her own body in order for the patient's decision-making to be informed. To the extent a medical professional may believe that an image may be helpful to the patient's decision-making, it may be appropriate to show images to the patient and to discuss them, either from the patient's own radiologic studies or de-identified images or artistic renderings of relevant anatomy. Certainly, patients themselves may choose to view radiologic or other images, particularly on the Internet, as part of their decision-making, but it is my opinion that it would violate medical ethics to force patients, against their will, to view images of their own bodies as part of the informed consent process.

31. For example, I know from my own experience that women with abnormal PAP smears are not required to view images of the abnormalities on their cervix in order to consent to medical treatment for that condition. Similarly, heart catheterization is an

invasive and serious medical procedure carrying substantial risks for patients, but physicians do not require patients choosing such a procedure to view an ultrasound or scan of their own hearts in order to provide informed consent.

32. It is widely recognized that truthful disclosure of certain details of medical procedures could harm patients and potentially undermine autonomous actions on their part. In a breadth of such cases, disclosure of potentially disturbing information (for instance, about the force required to open the chest of a cardiac patient) is not required to establish informed consent and in fact its provision is likely to undermine it.

33. To the extent that an ultrasound can be considered a visual or other type of decision aid, to my knowledge such aids have not been mandated by law or policy (except for laws like the Act). When such aids are used they are offered as enhancements, and patients are free to decline.

34. There is no basis in bioethics for treating patients seeking a pregnancy termination differently from patients seeking other types of medical care. Professional ethical standards uphold the primacy of the pregnant woman's health and autonomy interests, even when the pregnancy is wanted and continuing.

35. For instance, the ACOG Committee on Ethics holds that even when the actions of a pregnant woman threaten the well-being of a fetus, the woman's autonomous decisions should be respected. According to ACOG: "Concerns about the impact of maternal decisions on fetal well-being should be discussed in the context of medical evidence and understood within the context of each woman's broad social network,

cultural beliefs, and values. In the absence of extraordinary circumstances, circumstances that, in fact, the Committee on Ethics cannot currently imagine, judicial authority should not be used to implement treatment regimens aimed at protecting the fetus, for such actions violate the pregnant woman's autonomy." [Committee on Ethics, American Congress of Obstetricians and Gynecologists. Committee Opinion #321: Maternal Decision-Making, Ethics and the Law, *Obstetrics and Gynecology*. 2005;106:1127-37 2005]. In fact, the American Academy of Pediatrics and ACOG concur about the primacy of the pregnant woman's interests, and in a joint statement indicated that even when an intervention is available to improve fetal health, a pregnant woman's right to informed refusal must be respected fully." [American College of Obstetricians and Gynecologists Committee on Ethics and the American Academy of Pediatrics Committee on Bioethics. Maternal-Fetal Intervention and Fetal Care Centers. *Pediatrics* 2011;128: e473-8].

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 30, 2012

at Chapel Hill, NC.

Anne Drapkin Lyerly, M.D., M.A.